

Exhibit F

**Deposition of Swapam Roychowdhury
December 15, 2009**

Swapan Roychowdhury
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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: DIGITEK® PRODUCTS : MDL NO.
LIABILITY LITIGATION : 1968

(This document relates to all cases.)

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New York, New York
Tuesday, December 15, 2009

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Videotaped Deposition of SWAPAN
ROYCHOWDHURY, held at Harris Beach PLLC, 100
Wall Street, 24th Floor, on the above date,
beginning at 9:44 a.m., before Kimberly A.
Overwise, a Certified Realtime Reporter and
Notary Public.

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1 MR. ANDERTON: Are you saying
2 "fences"?

3 MR. MILLER: Yes.

4 MR. ANDERTON: Okay.

5 MR. MILLER: It might be the
6 wrong term.

7 MR. ANDERTON: I just wanted to
8 make sure I knew what word you were
9 saying.

10 BY MR. MILLER:

11 Q Okay. If you don't understand what
12 I'm saying, I'll --

13 A I don't understand "fences."

14 Q I've been in places before where
15 when you say somebody can't do something, he's
16 got a fence around him. So I don't know what
17 term they would use. Perhaps you didn't use
18 such a term.

19 Could all -- did you have a group of
20 chemists that were qualified to do content
21 uniformity testing, or were all chemists
22 capable of doing all tests? How did you
23 divide it up?

24 MR. ANDERTON: Objection.

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1 You may answer.

2 THE WITNESS: Well, some people
3 are more experienced on handling raw
4 material testing, which are basically
5 weight chemistry analysis. Some people
6 are more experienced on instrumental
7 analysis, like HPLCs. So accordingly,
8 the work was assigned.

9 BY MR. MILLER:

10 Q Okay. Let's just say something came
11 in for HPLC testing. That's high performance
12 liquid chromatography?

13 A Chromatography.

14 Q If it was a particular type of drug,
15 would you say, "Oh, no. That product needs to
16 go to this person"? Or once something came in
17 for HPLC, all HPLC analysts were capable of
18 testing that product?

19 MR. ANDERTON: Objection.

20 You may answer.

21 THE WITNESS: Basically any
22 HPLC chemist can handle all the product,
23 but certain products are very
24 technique-dependent.

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1 BY MR. MILLER:

2 Q Very technique?

3 A Technique. It may require liquid
4 extraction. Those are very
5 technique-dependent.

6 Q If a technique-dependent product
7 came in, did you have a specific tester or
8 group of testers that you liked to use?

9 A They are more experienced on that
10 product.

11 Q More experienced on that product?
12 What were some of the products that
13 were more technique-dependent?

14 MR. ANDERTON: Objection. I
15 instruct the witness not to answer or to
16 answer only with respect to Digitek.

17 BY MR. MILLER:

18 Q Was Digitek a technique-dependent
19 product?

20 A No.

21 Q So if Digitek came in, it could go
22 to any of the HPLC testers?

23 A That's correct.

24 Q And if there was a content

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1 uniformity test to be done on Digitek, it
2 could go to any analyst who was qualified to
3 do content uniformity?

4 A That's correct.

5 Q If Digitek came in to be tested for
6 stability, it could be accomplished by any lab
7 chemist who was qualified to do stability
8 testing?

9 A They are expected, yes.

10 Q And if Digitek came in for
11 friability testing, it could be handled by any
12 lab chemist who was qualified in friability?

13 A Who handled friability testing.

14 Q And if there was an assay for blend
15 test to be done, it could be handled for --
16 specifically for Digitek; it could be handled
17 by any chemist who was qualified to do assay
18 for blend testing?

19 A Yes.

20 Q And if a sample of Digitek came in
21 to be assay tested, it could be done by any
22 lab chemist who was qualified to do assay
23 testing?

24 A Repeat that again.

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1 Q And did you or anyone that reported
2 to you work on that action item?

3 A Yes. We had a program based on
4 QSIP. All the chemists were retraining. So
5 this document was updated probably based on
6 those training documents.

7 Q Okay. And when the analysts were
8 retrained, they were retrained about lab
9 notebooks across the board, not any particular
10 product; correct?

11 A Across the board.

12 Q Across the board?

13 A Documentation practices.

14 Q The problem you agree was identified
15 across the board, so the training was across
16 the board?

17 MR. ANDERTON: Objection.

18 BY MR. MILLER:

19 Q You can answer.

20 MR. ANDERTON: Wait.

21 Mischaracterizes his testimony.

22 You may answer.

23 THE WITNESS: The training was
24 given specifically in here what it

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1 mentioned, the documentation practices.
2 They were specifically instructed to
3 document every observations and all the
4 procedures they are following.

5 BY MR. MILLER:

6 Q For all products?

7 A All products, for any products.

8 Q Any product.

9 And "Procedures are in place where
10 all data generated during testing are entered
11 into the new lab notebooks."

12 Did I read that correctly?

13 A That's correct.

14 Q Do you understand what the action
15 item meant when it says "new lab notebooks"?
16 Were the lab notebooks changed or altered?

17 MR. ANDERTON: Objection.

18 You may answer.

19 THE WITNESS: Yes. We make it
20 more simpler, the new notebooks. Before
21 it was like 200 pages of bound book. And
22 we have different type of notebook, ready
23 lab notebook which is prenumbered.

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1 Q And seeing this document, does that
2 refresh your recollection on working on this
3 action item?

4 A Yes. We improved our OS
5 investigation procedures; that is, DOI QC-59.
6 And we improved to adequately investigate the
7 laboratory investigation.

8 Q And you would agree with me that if
9 a lab chemist is not properly investigating an
10 OOS, then that is an issue or problem with the
11 lab, not that one incident where it occurred;
12 is that correct?

13 MR. ANDERTON: Objection.

14 You may answer.

15 THE WITNESS: This is
16 interpretation of FDA investigator at
17 that time. Ideally I need to go back and
18 check what it says in QC-059 12 at that
19 time and what was the practice at that
20 time was followed.

21 If the chemists were following
22 that particular practices and procedures,
23 they are following the procedures. It
24 may not be liking of FDA investigator, so

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1 that's what their comments were that was
2 not, in their mind, it was not properly
3 conducted.

4 BY MR. MILLER:

5 Q Do you recall working on the action
6 items to rectify this situation?

7 A Yes. We updated our investigation
8 procedure.

9 Q And you updated investigation
10 procedures for all products?

11 A That's the lab procedure. That
12 involves all the products.

13 Q If we take a look at Observation 5
14 on the 483, it states that: "Input to and
15 output from the computer are not checked for
16 accuracy.

17 "Specifically, audits were not
18 conducted of the TotalChrom Data Acquisition
19 System used to run the HPLC instruments during
20 analysis of drug products. Sample injections,
21 processing methods, and sample weights were
22 not reviewed or verified for the accuracy of
23 reported sample results during testing of
24 in-process, finished product and stability